K062297

510(k) Summary
For
Amsco® V-PRO™ 1 Low Temperature Sterilization System

1. Submitter Information

OCT 4 2007

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Submission Date: August 4, 2006

2. Device Name

Trade Name: Amsco® V-PRO™ Low Temperature Sterilization System

Common/usual Name: Vapor Phase Hydrogen Peroxide Sterilizer

Classification Name: Sterilizer, Ethylene Oxide Gas

3. Predicate Device

Sterrad 100S Sterilization System

4. Description of Device

The STERIS Amsco V-PRO Low Temperature Sterilizer is a self contained stand-alone device, using vaporized hydrogen peroxide as the sterilant. The sterilizer is intended for use in the terminal sterilization of cleaned, rinsed, and dried, reusable metal and nonmetal medical devices used in healthcare facilities. The sterilization cycle operates at low pressure and temperatures, and is therefore suitable for processing medical devices sensitive to heat and moisture. The hydrogen peroxide vapor is generated by injecting aqueous hydrogen peroxide into a vaporization chamber where the solution is heated and converted to a vapor, and then introduced into the sterilizer chamber under negative pressure.

The equipment (hardware) for the V-PRO 1 Sterilizer is similar to that of the predicate device (Sterrad 100S Sterilizer System). The hardware consists of a welded frame onto which is mounted the sterilization chamber along with a variety of instruments and components, controls, piping, vacuum pump, housed in a covered frame of stainless steel panels. The V-PRO 1 Sterilizer also uses accessories such as disposable multiple use sterilant cartridge, reusable instrument trays, printer paper and ink cartridges.

5. Statement of Intended Use

The V-PRO 1 Low Temperature Sterilization System and Vaprox® HC Hydrogen Peroxide Sterilant (59%) are intended for use in terminal sterilization of cleaned, rinsed, and dried, reusable metal and nonmetal medical devices used in healthcare facilities.

The V-PRO 1 Low Temperature Sterilization System can sterilize*:

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

- Medical devices with a single stainless steel lumen with:
  - an inside diameter of 1 mm or larger and a length of a 125 mm or shorter
  - an inside diameter of 2 mm or larger and a length of 250 mm or shorter
  - an inside diameter of 3 mm or larger and a length of 400 mm or shorter

* The validation testing for all lumen sizes was conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

6. Effectiveness

Validation Testing

Testing was performed using the "overkill" method.

Pre-validation Testing

- Test Organism: *Geobacillus stearothermophilus*

- Process Variables and Parameters: Testing was conducted to characterize the effect of the process parameters on lethality. The four critical process parameters that may affect process lethality are chamber wall temperature, vaporizer temperature, injection pressure and injection weight. The level tested for each parameter was selected to provide a worst case situation for the test series and to be outside the abort levels or settings for the sterilizer. The study showed that process lethality was unaffected over the range of process parameters tested.

V-PRO 1 Sterilization System Process Validation

- Surface Sterilization of Medical Device Materials:

  The purpose of this study was to demonstrate the effectiveness of the V-PRO 1 Sterilizer using EOSL sterilant under ½ cycle parameters with *Geobacillus stearothermophilus* spores inoculated on a wide variety of medical device materials. Coupons made from these materials were cleaned, then inoculated with $>10^6$ *Geobacillus stearothermophilus* spores, the Most Resistant Organism (MRO), and dried for 1 hour.

  All of the coupons tested in the V-PRO 1 Sterilizer ½ cycles were sterile indicating sterile efficacy of all representative device materials using End of Shelf Life (EOSL) sterilant dose at ½ cycle conditions.

- Mated Surfaces:

  This study was designed to demonstrate the ability of the V-PRO 1 Sterilizer using EOSL sterilant to effectively sterilize mated or closely-opposed surfaces, a study was performed with metallic and polymer carriers and tested under half cycle conditions in the V-PRO 1 sterilization process. The materials used were stainless steel, Ultem, Radel, Delrin, and Noryl. These polymers were chosen because they are the most commonly used in nonmetallic reusable devices with mated surfaces.

  All of the coupons tested in the V-PRO 1 Sterilizer ½ cycles were sterile indicating sterile efficacy of all representative device materials using EOSL sterilant dose.

- Lumen Sterilization - Worst Case Lumen Size:

  Microbial efficacy testing was performed to determine the most difficult of the V-PRO 1 System's lumen claims to sterilize. The lumen sizes tested were 1 x 125 mm, 2 x 250 mm, and 3 x 400 mm stainless steel.

  Worst case lumen testing was performed in the V-PRO 1 Sterilizer at ½ cycle operation parameters using a reduced hydrogen peroxide injection weight of the EOSL sterilant; that is at < the standard 2.1g hydrogen peroxide injection weight.

  Results indicate that the 3 x 400 mm is the worst case, i.e. most difficult to sterilize, of the lumens size claims for the V-PRO 1 Sterilizer.

- Half Cycle Verification at Multiple Peroxide Injection Weights – Worse Case Lumen Size:

  Five injection weights, 0.121, 0.607, 1.214, 1.457, and 2.1g, were used to test the worst case lumen size, 3 x 400 mm, at ½ cycle parameters and EOSL sterilant to demonstrate the microbial efficacy of the V-PRO 1 Sterilizer.

  At the standard hydrogen peroxide injection weight of 2.1g and the reduced injection weight of 1.457g, all lumens were sterile.

- Half Cycle Verification of Lumen Claims:

  The testing was performed to demonstrate the microbial efficacy of the V-PRO 1 Sterilizer under ½ cycle parameters and EOSL sterilant using 1 x 125 mm, 2 x 250, and 3 x 400 mm stainless steel lumens.

  All lumens of each size were sterile after the V-PRO 1 ½ cycle using EOSL sterilant.

- Tyvek/Mylar Pouched Device Sterilization:

  The purpose of this validation study was to demonstrate efficacy of the V-PRO 1 Sterilizer using EOSL sterilant at ½ cycle parameters using an alternative device/instrument packaging method, individual placement in Tyvek/Mylar pouches rather than arranged in a wrapped sterilization tray. Test articles of lumen sizes of 1 x 125 mm, 2 x 250 mm, and 3 x 400 mm stainless steel were used.

  All lumens of each size were sterile after the V-PRO 1 ½ cycle using EOSL sterilant.

- Supporting Microbiological Testing:

  AOAC Sporicidal carrier testing was performed in the V-PRO 1 Sterilizer per the guidelines provided in the Official Methods of Analysis of the AOAC International Association of Official Chemists, 17th Edition, 2000, AOAC Official Method 966.04 "*Sporicidal Activity of Disinfectant*". None of the carriers demonstrated growth.

- Modified Total Kill Endpoint Bracket Testing:

  Total Kill Endpoint Bracketing is testing that evaluates the sterilant exposure time from ¼ to ¾ of the total full cycle exposure with all sterile results expected after ½ of the cycle. The V-PRO 1 Sterilizer full cycle consists of four fixed time pulses using 2.1g peroxide injected per pulse.

For this testing, the V-PRO 1 Sterilizer was modified to perform cycles consisting of 1, 3, and 4 pulses to evaluate the total kill endpoint. Two pulse cycles were evaluated in the *Half Cycle Verification at Multiple Peroxide Injection Weights* study using the worst case lumen size of 3 x 400 mm.

An all kill endpoint was demonstrated with sterile results at the 2, 3 and 4 pulse cycles in the V-PRO 1 Sterilizer. These results demonstrate a SAL of 10^{-6} for the complete V-PRO 1 sterilization process.

- Toxicity Testing of Processed Materials:

  Cytotoxicity and *in vivo* biocompatibility testing of materials processed in the V-PRO 1 Sterilizer showed that the sterilization process leaves no toxic sterilant residuals on the materials.

- Simulated Use Testing:

  Testing was performed to confirm sterility of medical device outer surface sites and lumens after processing in V-PRO 1 Low Temperature Sterilization System at full cycle parameters using EOSL sterilant. Devices representative of surface features and lumen claims for the V-PRO 1 Low Temperature Sterilization System were selected for the Simulated Use testing.

  A total of 16 devices with 19 inoculated sites (multiple sites per device, lumens and surface sites) were tested in each cycle with three replicate cycles performed with and without cleaning conditions. This equates to a total of 114 device sites tested for sterile efficacy with results showing all sites sterile for a full cycle in the V-PRO 1 Low Temperature Sterilization System. The simulated use device load was similar in device make up and weight as the validation load.

- In-Use Sterility Testing:

  Testing was performed to confirm sterility of targeted medical device outer surface sites and lumens that were clinically soiled, manually cleaned, dried, packaged, and processed in the V-PRO 1 Low Temperature Sterilization System. Devices tested in this study were used in routine surgeries at a local hospital and included stainless steel devices with open surfaces, mated or hinged surfaces and stainless steel lumened devices with dimensions that were approximate to the V-PRO 1 Low Temperature Sterilization System's claims. The in use device load was similar in device make up as the validation load.

  The recoverable bioburden levels before and after cleaning ranged from 0 to 64 CFU. These recoverable bioburden levels are within the published recovery range for critical medical devices. All sites for all three trials were

sterile after processing the pre-cleaned devices together in the V-PRO 1 Low Temperature Sterilization System.

A total of 12 devices were tested in this study with 14 inoculated sites evaluated. This equates to a total of 42 device sites tested for sterile efficacy with results showing all sites sterile for a full cycle in the V-PRO 1 Low Temperature Sterilization System.

- Software Validation:

  The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document "*Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices*".

7. Overall Performance Conclusions

The non-clinical studies demonstrate that the V-PRO 1 Low Temperature Sterilization System is safe and effective for sterilization of heat and moisture sensitive medical devices within the indications for use for the sterilizer and established equivalence of the V-PRO 1 Low Temperature Sterilization System to the predicate device, the Sterrad 100S Sterilization System.

8. Safety

- Software Risk Management Plan and Risk Analysis including Failure Mode Effects and Critical Analysis (FMECA) has been performed.

- Equipment Risk Management Plan and Risk Analysis including Fault Tree Analysis (FTA) and Failure Mode Effects and Critical Analysis (FMECA) has been performed.

- The V-PRO 1 Low Temperature Sterilization System meets the applicable requirement for the following standards as certified by UL:
  - Underwriters Laboratories (UL) Standard 61010-1 Second Edition
  - Canadian Standard Association (CSA) Can/CSA 22.2 No. 1010.1-92, Second Edition

- Governing Directive for the Affixing of the CD mark:
  - Medical Device Directive (MDD) 93/42/EEC

- Standards applied to demonstrate conformity to the directives:
  - EN61010-1
  - EN60601-1-2

User Information

- Operator Manual
- Service Manual
- Installation Instructions
- Technical Data Sheet

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Patrick J. McCullagh
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STERIS Corporation
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OCT 4 2007

Re: K062297
Trade/Device Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System
Regulation Number: 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: July 31, 2007
Received: August 1, 2007

Dear Dr. McCullagh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062297

Device Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System

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Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K062297